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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PFIZER INC., PHARMACIA & UPJOHN COMPANY LLC, and PFIZER HEALTH AB, Plaintiffs and Counterclaim Defendants, -v- IMPAX LABORATORIES, INC., Defendant and Counterclaim Plaintiff.	Case No. 1:08-cv-2177(LTS)(KNF) ELECTRONICALLY FILED

ANSWER TO THE COMPLAINT AND COUNTERCLAIMS

Defendant Impax Laboratories, Inc. ("Impax") hereby responds to the Complaint filed by Pfizer Inc., Pharmacia & Upjohn Company LLC and Pfizer Health AB (collectively, "Plaintiffs" or "Pfizer") on March 4, 2008, as follows:

THE PARTIES

1. Impax admits the allegations set forth in paragraph 1 of the Complaint.

2. Impax admits the allegations set forth in paragraph 2 of the Complaint.

3. Impax admits the allegations set forth in paragraph 3 of the Complaint.

4. Impax admits the allegations set forth in paragraph 4 of the Complaint.

JURISDICTION AND VENUE

5. Impax admits that this Court has exclusive subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. Impax admits that this Court has personal jurisdiction over Impax.

7. Impax admits that venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

U.S. Patent No. 5,382,600

8. Impax admits that U.S. Patent No. 5,382,600 (the "'600 Patent") is entitled "3,3-Diphenylpropylamines and Pharmaceutical Compositions Thereof" and the face of the '600 Patent shows that it was issued by the United States Patent and Trademark Office on January 17, 1995. Impax admits that Pharmacia Aktiebolag is listed as the assignee on the face of the '600 Patent. Impax admits that what is attached as Exhibit A to the Complaint appears to be a true and correct copy of the '600 Patent. Impax lacks information and knowledge sufficient to form a belief as to the remaining allegations set forth in paragraph 8 of the Complaint.

9. The allegations in paragraph 9 state a conclusion of law to which no response is required. Further answering, Impax states that the '600 Patent speaks for itself.

U.S. Patent No. 6,630,162

10. Impax admits that U.S. Patent No. 6,630,162 (the "'162 Patent") is entitled "Pharmaceutical Formulation and its Use" and the face of the '162 Patent shows that it was issued by the United States Patent and Trademark Office on October 7, 2003. Impax admits that Pharmacia AB is listed as the assignee on the face of the '162 Patent. Impax admits that what is attached as Exhibit B to the Complaint appears to be a true and correct copy of the '162 Patent.

Impax lacks information and knowledge sufficient to form a belief as to the remaining allegations set forth in paragraph 10 of the Complaint.

11. The allegations in paragraph 11 state a conclusion of law to which no response is required. Further answering, Impax states that the '162 Patent speaks for itself.

U.S. Patent No. 6,770,295

12. Impax admits that U.S. Patent No. 6,770,295 (the "'295 Patent") is entitled "Therapeutic Formulation for Administration Tolterodine with Controlled Release" and the face of the '295 Patent shows that it was issued by the United States Patent and Trademark Office on August 3, 2004. Impax admits that Pharmacia AB is listed as the assignee on the face of the '295 Patent. Impax admits that what is attached as Exhibit C to the Complaint appears to be a true and correct copy of the '295 Patent. Impax lacks information and knowledge sufficient to form a belief as to the remaining allegations set forth in paragraph 12 of the Complaint.

13. The allegations in paragraph 13 state a conclusion of law to which no response is required. Further answering, Impax states that the '295 Patent speaks for itself.

Detrol LA®

14. Impax admits that the electronic version of the Food and Drug Administration ("FDA") publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") identifies Pharmacia & Upjohn Company LLC as the holder of an approved New Drug Application ("NDA") for tolterodine tartrate extended release capsules, in 2 and 4 mg dosages. Impax further admits that the Orange Book identifies the propriety name of tolterodine tartrate extended release capsules, in 2 and 4 mg dosages, as Detrol LA®. Impax lacks information and knowledge sufficient to form a belief as to the remaining allegations set forth in paragraph 14 of the Complaint.

15. Impax admits that the Orange Book lists the '600, '162 and '295 Patents with respect to Detrol LA®. Impax lacks information and knowledge sufficient to form a belief as to the remaining allegations set forth in paragraph 15 of the Complaint.

Impax's ANDA

16. Impax admits that it submitted Abbreviated New Drug Application ("ANDA") No. 90-235 ("Impax's ANDA") seeking FDA approval to engage in the manufacture, use or sale of its Tolterodine Tartrate Extended-Release (ER) Capsules, 4 mg ("Impax's Tolterodine ER Capsules").

17. Impax admits that its ANDA No. 90-235 refers to the Detrol LA NDA and contains data that Impax believes demonstrates the bioequivalence of Impax's Tolterodine ER Capsules and Detrol LA®. Impax denies the remaining allegations set forth in paragraph 17 of the Complaint.

18. Impax admits that it sent a "Patent Certification Notice" ("Impax's Notice Letter") dated January 29, 2008 to Pfizer Inc. and others, stating that Impax had submitted its ANDA No. 90-235 for Impax's Tolterodine ER Capsules. Impax admits that Impax's Notice Letter stated that Impax's ANDA contains a Paragraph IV certification with respect to the '600, '162 and '295 Patents. Impax further admits that Impax included in its Notice Letter a detailed statement of the factual and legal bases that the '600, '162 and '295 Patents are invalid, unenforceable or not infringed. Impax denies the remaining allegations set forth in paragraph 18 of the Complaint.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 5,382,600

19. With respect to paragraph 19 of the Complaint, Impax repeats and incorporates by reference paragraphs 1-18 herein.

20. Impax denies the allegations contained in paragraph 20 of the Complaint.

21. Impax denies the allegations contained in paragraph 21 of the Complaint.

22. Impax denies the allegations contained in paragraph 22 of the Complaint.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,630,162

23. With respect to paragraph 23 of the Complaint, Impax repeats and incorporates by reference paragraphs 1-18 herein.

24. Impax denies the allegations contained in paragraph 24 of the Complaint.

25. Impax denies the allegations contained in paragraph 25 of the Complaint.

26. Impax denies the allegations contained in paragraph 26 of the Complaint.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,770,295

27. With respect to paragraph 27 of the Complaint, Impax repeats and incorporates by reference paragraphs 1-18 herein.

28. Impax denies the allegations contained in paragraph 28 of the Complaint.

29. Impax denies the allegations contained in paragraph 29 of the Complaint.

30. Impax denies the allegations contained in paragraph 30 of the Complaint.

AFFIRMATIVE DEFENSES

First Affirmative Defense

31. All the claims of the ‘600 Patent are invalid under 35 U.S.C. §§ 101, 102, 103 and/or 112.

Second Affirmative Defense

32. All the claims of the ‘162 Patent are invalid under 35 U.S.C. §§ 101, 102, 103 and/or 112.

Third Affirmative Defense

33. All the claims of the '295 Patent are invalid under 35 U.S.C. §§ 101, 102, 103 and/or 112.

Fourth Affirmative Defense

34. The manufacture, use, sale, offer for sale or importation of Impax's Tolterodine Tratrate Extended Release Capsules, 4 mg, does not and will not infringe any valid claim of the '600 Patent.

Fifth Affirmative Defense

35. The manufacture, use, sale, offer for sale or importation of Impax's Tolterodine Tratrate Extended Release Capsules, 4 mg, does not and will not infringe any valid claim of the '162 Patent.

Sixth Affirmative Defense

36. The manufacture, use, sale, offer for sale or importation of Impax's Tolterodine Tratrate Extended Release Capsules, 4 mg, does not and will not infringe any valid claim of the '295 Patent.

Seventh Affirmative Defense

37. Based on what is set forth below in Counterclaim 7, which Impax incorporates by reference herein, the '600 Patent is unenforceable under the doctrine of inequitable conduct.

ANSWER TO PRAYER FOR RELIEF

Impax denies that Plaintiffs are entitled to the judgment and relief prayed for in paragraphs A through H under the heading "PRAYER FOR RELIEF" in the Complaint.

COUNTERCLAIMS

Impax Laboratories, Inc. ("Impax") for its counterclaims against Pfizer Inc., Pharmacia & Upjohn Company LLC and Pfizer Health AB (collectively, "Counterclaim Defendants" or "Pfizer"), alleges and avers as follows:

THE PARTIES

1. Impax is a corporation organized and existing under the laws of the State of Delaware, and having a place of business at 30831 Huntwood Avenue, Haywood, California.

2. Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 235 East 42nd Street, New York, NY.

3. Pharmacia & Upjohn Company LLC is a corporation organized and existing under the laws of the State of Delaware having a place of business at 7000 Portage Road, Kalamazoo, MI. Pfizer Inc. is the ultimate parent of Pharmacia & Upjohn Company LLC.

4. Pfizer Health AB is a company organized and existing under the laws of Sweden, having a place of business at SE-112 87, Stockholm, Sweden. Pfizer, Inc. is the ultimate parent of Pfizer Health AB.

JURISDICTION AND VENUE

5. These Counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1 et seq.

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. This Court has personal jurisdiction over Pfizer at least for the reason that Pfizer has submitted to the jurisdiction of this Court by virtue of filing its Complaint.

8. Venue is proper in this judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE CONTROVERSY

U.S. Patents No. 5,382,600, 6,630,162 and 6,770,295

9. U.S. Patent No. 5,382,600 (the "'600 Patent"), entitled "3,3-Diphenylpropylamines and Pharmaceutical Compositions Thereof," was issued by the United States Patent and Trademark Office on January 17, 1995. Pharmacia Aktiebolag is listed as the assignee on the face of the '600 Patent.

10. U.S. Patent No. 6,630,162 (the "'162 Patent"), entitled "Pharmaceutical Formulation and its Use," was issued by the United States Patent and Trademark Office on October 7, 2003. Pharmacia AB is listed as the assignee on the face of the '162 Patent.

11. U.S. Patent No. 6,770,295 (the "'295 Patent"), entitled "Therapeutic Formulation for Administration Tolterodine with Controlled Release," was issued by the United States Patent and Trademark Office on August 3, 2004. Pharmacia AB is listed as the assignee on the face of the '295 Patent.

Detrol LA®

12. The electronic version of the Food and Drug Administration ("FDA") publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") identifies Pharmacia & Upjohn Company LLC as the holder of an approved New Drug Application ("NDA") for tolterodine tartrate extended release capsules, in 2 and 4 mg dosages. The Orange Book identifies the propriety name of tolterodine tartrate extended release capsules, in 2 and 4 mg dosages, as Detrol LA®.

13. The Orange Book lists the '600, '162 and '295 Patents with respect to Detrol LA®.

Impax's ANDA No. 90-235

14. Pursuant to the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 355(j), Impax submitted Abbreviated New Drug Application ("ANDA") No. 90-235 ("Impax's ANDA") seeking FDA approval to engage in the manufacture, use or sale of its Tolterodine Tartrate Extended-Release (ER) Capsules, 4 mg ("Impax's Tolterodine ER Capsules").

15. Impax's ANDA No. 90-235 refers to the Detrol LA NDA and contains data that Impax believes to demonstrate the bioequivalence of Impax's Tolterodine ER Capsules and Detrol LA®.

16. Impax sent a "Patent Certification Notice" ("Impax's Notice Letter") dated January 29, 2008 to Pfizer Inc. and others, stating that Impax had submitted its ANDA No. 90-235 for Impax's Tolterodine ER Capsules. Impax's Notice Letter stated that Impax's ANDA contains a Paragraph IV certification that Impax's manufacture, use, importation, sale or offer for sale of Impax's Tolterodine ER Capsules will not infringe any valid or enforceable claim of the '600, '162 and '295 Patents. Impax provided, in company with its Notice Letter, a detailed statement of the factual and legal bases that the '600, '162 and '295 Patents are invalid, unenforceable or not infringed.

Pfizer's Infringement Claim

17. After receiving Impax's Notice Letter, Pfizer filed the present action against Impax on March 4, 2008.

18. In its Complaint, Pfizer asserts ownership of the '600, the '162 and the '295 Patents.

19. Pfizer alleges that Impax has infringed the '600, '162 and '295 Patents by submitting its ANDA No. 90-235.

20. Pfizer also alleges that Impax will further infringe the '600, '162 and '295 Patents if Impax commercially makes, uses, offers to sell, or sells Impax's Tolterodine ER Capsules within the United States, or imports Impax's Tolterodine ER Capsules into the United States.

21. Based on the foregoing, there is an actual and immediate controversy between Impax and Pfizer concerning whether Impax's manufacture, use, importation, sale or offer for sale of Impax's Tolterodine ER Capsules will infringe any claim of the '600, '162 and '295 Patents and whether such patents are valid and enforceable.

22. Upon information and belief, Pfizer's charge of infringement, after being advised by Impax as to why there is no basis for such charge, and other conduct yet to be discovered, renders this case exceptional within the meaning of 35 U.S.C. § 285.

COUNTERCLAIM 1

Declaratory Judgment of Invalidity of the '600 Patent

23. Impax realleges paragraphs 1-22 above as fully set forth herein.

24. An actual controversy exists between Impax and Pfizer concerning the validity of the '600 Patent, which requires a declaration of rights by this Court.

25. All claims of the '600 Patent are invalid for failing to comply with the requirements of the Patent Laws of the United States, 35 U.S.C. §§ 101, 102, 103 and/or 112.

COUNTERCLAIM 2

Declaratory Judgment of Invalidity of the '162 Patent

26. Impax realleges paragraphs 1-22 above as fully set forth herein.

27. An actual controversy exists between Impax and Pfizer concerning the validity of the '162 Patent, which requires a declaration of rights by this Court.

28. All claims of the '162 Patent are invalid for failing to comply with the requirements of the Patent Laws of the United States, 35 U.S.C. §§ 101, 102, 103 and/or 112.

COUNTERCLAIM 3

Declaratory Judgment of Invalidity of the '295 Patent

29. Impax realleges paragraphs 1-22 above as fully set forth herein.

30. An actual controversy exists between Impax and Pfizer concerning the validity of the '295 Patent, which requires a declaration of rights by this Court.

31. All claims of the '295 Patent are invalid for failing to comply with the requirements of the Patent Laws of the United States, 35 U.S.C. §§ 101, 102, 103 and/or 112.

COUNTERCLAIM 4

Declaratory Judgment of Non-Infringement of the '600 Patent

32. Impax realleges paragraphs 1-22 above as fully set forth herein.

33. An actual controversy exists between Impax and Pfizer concerning the infringement of the '600 Patent, which requires a declaration of rights by this Court.

34. The manufacture, use, offer for sale, sale or importation of Impax's Tolterodine ER Capsules will not infringe any valid claim of the '600 Patent.

COUNTERCLAIM 5

Declaratory Judgment of Non-Infringement of the '162 Patent

35. Impax realleges paragraphs 1-22 above as fully set forth herein.

36. An actual controversy exists between Impax and Pfizer concerning the infringement of the '162 Patent, which requires a declaration of rights by this Court.

37. The manufacture, use, offer for sale, sale or importation of Impax's Tolterodine ER Capsules will not infringe any valid claim of the '162 Patent.

COUNTERCLAIM 6

Declaratory Judgment of Non-Infringement of the '295 Patent

38. Impax realleges paragraphs 1-22 above as fully set forth herein.

39. An actual controversy exists between Impax and Pfizer concerning the infringement of the '295 Patent, which requires a declaration of rights by this Court.

40. The manufacture, use, offer for sale, sale or importation of Impax's Tolterodine ER Capsules will not infringe any valid claim of the '295 Patent.

COUNTERCLAIM 7

Declaratory Judgment of Unenforceability of the '600 Patent

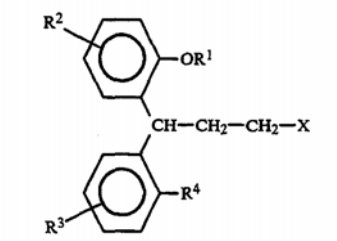
41. Impax realleges paragraphs 1-22 above as fully set forth herein.

42. An actual controversy exists between Impax and Pfizer concerning the enforceability of the '600 Patent, which requires a declaration of rights by this Court.

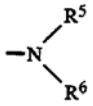
a. Introduction

43. This matter concerns, inter alia, United States Patent No. 5,382,600 (the "'600 Patent"), entitled "3,3-Diphenylpropylamines and Pharmaceutical Compositions Thereof," issued by the United States Patent and Trademark Office ("PTO") on January 17, 1995.

44. The ‘600 Patent claims diphenylpropylamine compounds of formula I:



wherein R^1 signifies hydrogen or methyl, R^2, R^3 and R^4 independently signify hydrogen, methyl, methoxy, hydroxy, carbamoyl, sulphamoyl or halogen, and X represents a tertiary amino group of formula II



wherein each of R^5 and R^6 independently signifies C_{1-6} alkyl, which may be joined to form a ring with the amine nitrogen and each of which may carry a hydroxy substituent, or adamantyl, and wherein R^5 and R^6 together contain at least three carbon atoms, preferably at least 4 carbon atoms, their salts with physiologically acceptable acids and, when the compounds can be in the form of optical isomers, the racemic mixture and the individual enantiomers.

45. The ‘600 Patent issued from U.S. Patent Application Serial No. 07/810,185 (the “‘185 Application”), filed on December 19, 1991. The ‘185 Application is a continuation of Application Serial No. 07/543,767 (the “‘767 Application”), filed September 24, 1990, now abandoned, which was originally filed as an International Patent Cooperation Treaty (“PCT”) Application No. PCT/SE89/00016 (the “‘016 PCT Application”), filed January 20, 1989 and published as WO 89/06644 on July 27, 1989. The ‘016 PCT Application claimed priority to a Swedish Application No. 8800207-6, filed January 22, 1988.

46. The ‘600 Patent names Nils A. Jönsson, Bengt A. Sparf, Lembit Mikiver, Pinchas Moses, Lisbet Nilvebrant, and Gunilla Glas as inventors.

47. Upon information and belief, patent attorneys and/or agents, including Kummelsten, Per, Arne et al. at Uppsala Patentbyra in Uppsala, Sweden and Bjorn Widen,

participated in the prosecution of the ‘600 Patent and related applications.

48. The named inventors, their agents/attorneys and others who had substantive involvement in the prosecution of the ‘600 Patent (collectively, the “Applicants”) owed a duty of candor and disclosure to the PTO under 37 C.F.R. § 1.56 during the prosecution of the ‘600 Patent.

49. The Applicants breached their duty of candor and disclosure by failing to disclose a German Patent No. 1216318 (the “German ‘318 Patent”) and a Swedish Patent No. 300 822 (the “Swedish ‘822 Patent”) to the PTO during the prosecution of the ‘600 Patent, with an intent to deceive the PTO. Accordingly, the ‘600 Patent is rendered unenforceable under the doctrine of inequitable conduct.

b. The Applicants’ Failure to Disclose the German ‘318 Patent

50. During prosecution of the ‘185 Application, the Examiner rejected claims 1- 4, 6 and 9-15 “under 35 U.S.C. § 103 as being unpatentable over the German, British and U.S. patents and the Chemical Abstracts article cited in the corresponding [the ‘016 PCT Application]” in an Office Action dated July 10, 1992. The Examiner requested “copies of the German and British patents be supplied to complete the record.” The Examiner also requested the references during the examination of the parent ‘767 Application.

51. The International Search Report (ISR) of the ‘016 PCT Application cites one Swedish patent (SE 215 499), one Danish patent (DK 111 894), one U.S. patent (3,446,901), two British patents (GB 1 169 945 and GB 1 169 944) and one Chemical Abstracts reference (Vol. 97 (1982) 120105N). All the cited references, except the Swedish patent, are designated as type “X” references on the ISR. A type “X” reference is defined in the ISR as a “document of particular relevance: the claimed invention cannot be considered novel or cannot be considered

to involve an inventive step." The ISR does not cite any German patent.

52. However, Danish Patent No. 111 894 (the "Danish '894 Patent"), issued October 21, 1968, claimed priority to German Patent Application No. K48245, filed in November 15, 1962, which issued as the German '318 Patent on May 12, 1966. The German '318 Patent is prior art to the '600 Patent.

53. In a response dated July 11, 1993, the Applicants argued that the cited references did not render obvious the claimed invention of the '185 Application. In particular, the Applicants argued that the Danish '894 Patent did not teach placing a hydroxyl or alkoxy substituent in the ortho position of the phenyl rings and therefore did not render the claims obvious. In an Office Action dated February 27, 1993, the Examiner accepted the Applicants' arguments as overcoming the prior art Danish '894 Patent.

54. The Applicants attached "copies of the Danish and British patents cited in the corresponding PCT application" to their response dated July 11, 1993. But the Applicants did not provide a copy of the German '318 Patent or any other German patent, throughout the prosecution of the '185 Application.

55. The Applicants had knowledge of the German '318 patent during the prosecution of the '185 Application, because the Danish '894 Patent and the German '318 Patent claim priority to the same parent application and the Applicants provided a copy of the Danish '894 patent to the Examiner.

56. Moreover, some of the Applicants also had knowledge of the German '318 Patent from their involvement in a related PCT application, PCT Application No. SE93/00927 (the "PCT '927 Application"), filed November 5, 1993 and published as WO 94/11337 on May 26, 1994.

57. The PCT ‘927 Application and the ‘185 Application have three inventors in common, namely, Pinchas Moses, Lisbet Nilvebrant and Bengt A. Sparf. In addition, the PCT ‘927 Application was prosecuted by Björn Widen, an attorney who, upon information and belief, participated in the prosecution of the ‘016 PCT Application and the national applications based on the ‘016 PCT Application.

58. The PCT ‘927 Application, entitled “Novel 3,3-diphenylpropylamines, their use and preparation,” cites WO 89/06644 and claims compounds of the same generic structure as those claimed in the ‘185 Application. The compounds claimed in the PCT ‘927 Application differ from those claimed in the ‘185 Application merely by one substituent group – in the ‘185 application the R^2 group is “hydrogen, methyl, methoxy, hydroxyl, carbamoyl, sulphamoyl or halogen,” while in the PCT ‘927 Application the corresponding substituent is specified as a hydroxymethyl group.

59. The ISR of the PCT ‘927 Application lists the German ‘318 Patent, WO 8906644 and the two British patents, all designated as type “X” references. The ISR was mailed to inventors Sparf, Moses and Nilvebrant and attorney Widen on February 7, 1994, while the ‘185 Application was pending and a response to a final Office Action dated October 22, 1993 was due from the Applicants.

60. Therefore, during the prosecution of the ‘185 Application, inventors Sparf, Moses and Nilvebrant and attorney Widen also had knowledge of the German ‘318 Patent through their involvement in the prosecution of the PCT ‘927 Application.

61. Despite their knowledge of the German ‘318 Patent, the Applicants failed to disclose the German ‘318 Patent to the PTO during the prosecution of the ‘185 Application.

62. A reasonable PTO examiner would have considered the German ‘318 Patent

highly material to the patentability of the ‘185 Application, because the German ‘318 Patent disclosed compounds of the same generic structure to those claimed in the ‘185 Application, and therefore anticipates the claims of the ‘185 Application and/or renders the claims of the ‘185 Application obvious.

63. Were the German ‘318 Patent disclosed, a reasonable PTO examiner would have found that the teachings of German ‘318 Patent are inconsistent with and cannot be distinguished by arguments made by the Applicants during the prosecution of the ‘185 Application.

64. Specifically, in their response to the Office Action dated July 11, 1993, the Applicants argued that the prior art Danish ‘894 Patent did not teach placing a hydroxyl or alkoxy substituent in the ortho position of the phenyl ring and therefore the claims were patentable over the Danish ‘894 Patent. The German ‘318 Patent, however, disclosed compounds with alkoxy substituent in the ortho position of the phenyl ring. Therefore, were the German ‘318 Patent disclosed to a reasonable examiner, the Applicants could not have overcome the rejection by the same argument they made during the prosecution of the ‘185 Application.

65. The high materiality of the German ‘318 Patent is also evidenced by the fact that the German ‘318 Patent was designated as a type “X” reference in the ISR of the PCT ‘927 Application, which claims compounds of the same generic structure to those claimed in the ‘185 Application, with the exception of one substituent group.

66. Applicants were aware of the high materiality of the German ‘318 Patent during the prosecution of the ‘185 Application, because they knew that (1) the German ‘318 Patent described compounds of the same generic structure to those claimed in the ‘185 Application, and therefore anticipates the claims of the ‘185 Application and/or renders the claims of the ‘185 Application obvious; (2) the German ‘318 Patent described compounds having an alkoxy

substituent in the ortho position of the phenyl ring, which is inconsistent with and undermines Applicants' argument to distinguish the claims of the '185 Application from the prior art Danish '894 Patent; and (3) the German '318 Patent was designated as type "X" reference in the ISR of the closely related PCT '927 Application.

67. Moreover, the Applicants knew that the argument they made in overcoming the prior art Danish '894 patent would not have distinguished the German '318 Patent, which disclosed an alkoxy substituent in the ortho position of the phenyl rings. Despite the Examiner's request for the German patent, Applicants did not provide a copy of the German '318 patent to the Examiner. Instead, the Applicants provided the Examiner a copy of the Danish '894 Patent.

68. Therefore, despite their knowledge of the prior art German '318 Patent and its high degree of materiality, the Applicants failed to disclose the German '318 Patent to the PTO, with the intent to deceive the PTO. Accordingly, the Applicants breached their duty of candor under 37 C.F.R. § 1.56 and engaged in inequitable conduct in prosecuting the '185 Application, which renders the '600 Patent unenforceable.

c. The Applicants' Failure to Disclose the Swedish '822 Patent

69. During the prosecution of the '185 Application, the Applicants also failed to disclose to the Examiner the Swedish '822 Patent, filed November 14, 1963 and issued May 13, 1968. The Swedish '822 Patent is prior art to the '600 Patent.

70. The Swedish '822 Patent claims priority to the same parent application as the Danish '894 Patent and the German '318 Patent, *i.e.*, German Patent Application No. K48245, filed November 15, 1962.

71. The Swedish '822 Patent disclosed compounds of the same generic structure as the German '318 Patent and the Danish '894 Patent. However, like the German '318 Patent but

unlike the Danish ‘894 Patent, the Swedish ‘822 Patent disclosed compounds with alkoxy substituent in the ortho position of the phenyl ring.

72. The Applicants never disclosed the Swedish ‘822 Patent to the PTO during the prosecution of the ‘185 Application.

73. The Applicants of the ‘185 Application had knowledge of the Swedish ‘822 Patent during the prosecution of the ‘185 Application, because the Danish ‘894 patent and Swedish ‘822 patent claim priority to the same parent application and the Applicants provided a copy of the Danish ‘894 patent to the Examiner.

74. Moreover, because the Swedish ‘822 Patent pertains to compounds of the same generic structure as the ‘185 Application and was issued in Swedish language by the Swedish Patent Office, where the Applicants are Swedish nationals and the original priority application of the ‘185 Application was filed as a Swedish application, the Applicants should have had knowledge of the Swedish ‘822 Patent.

75. A reasonable PTO examiner would have considered the Swedish ‘822 Patent highly material to the patentability of the ‘185 Application, because like the German ‘318 Patent, the Swedish ‘822 Patent disclosed compounds of the same generic structure to those claimed in the ‘185 Application, and therefore anticipates the claims of the ‘185 Application and/or renders the claims of the ‘185 Application obvious.

76. Were the Swedish ‘822 Patent disclosed, a reasonable PTO examiner would have found that the teachings of Swedish ‘822 Patent are inconsistent with and cannot be distinguished by arguments made by the Applicants during the prosecution of the ‘185 Application.

77. Specifically, in their response to the Office Action dated July 11, 1993, the

Applicants argued that the prior art Danish ‘894 patent did not teach placing a hydroxyl or alkoxy substituent in the ortho position of the phenyl ring and therefore the claims of the ‘185 Application were patentable over the Danish ‘894 Patent. The Swedish ‘822 Patent, however, disclosed compounds with alkoxy substituent in the ortho position of the phenyl ring. Therefore, were the Swedish ‘822 Patent disclosed to a reasonable examiner, the Applicants could not have overcome the rejection by the same argument they made during the prosecution of the ‘185 Application.

78. Applicants were aware of the high materiality of the Swedish ‘822 Patent during the prosecution of the ‘185 Application, because they knew that the Swedish ‘822 Patent described compounds of the same generic structure to those claimed in the ‘185 Application, and therefore anticipates the claims of the ‘185 Application and/or renders the claims of the ‘185 Application obvious.

79. Moreover, the Applicants knew that the Swedish ‘822 Patent described compounds having an alkoxy substituent in the ortho position of the phenyl ring, which is inconsistent with and undermines Applicants’ argument to distinguish the claims of the ‘185 Application from the prior art Danish ‘894 Patent.

80. Therefore, despite their knowledge of the prior art Swedish ‘822 Patent and its high degree of materiality, the Applicants failed to disclose the Swedish ‘822 Patent to the PTO, with the intent to deceive the PTO. Accordingly, the Applicants breached their duty of candor under 37 C.F.R. § 1.56 and engaged in inequitable conduct in prosecuting the ‘185 Application, which renders the ‘600 Patent unenforceable.

81. Therefore, the manufacture, use, offer for sale, sale or importation of Impax’s Tolterodine ER Capsules will not infringe the ‘600 Patent.

PRAYER FOR RELIEF

Wherefore, Impax prays that this Court:

A. Enter judgment that Impax's Tolterodine ER Capsules do not infringe any valid or enforceable claim of U.S. Patent No. 5,382,600;

B. Enter judgment that Impax's Tolterodine ER Capsules do not infringe any valid or enforceable claim of U.S. Patent No. 6,630,162;

C. Enter judgment that Impax's Tolterodine ER Capsules do not infringe any valid or enforceable claim of U.S. Patent No. 6,770,295;

D. Enter declaratory judgment that U.S. Patent No. 5,382,600 is invalid;

E. Enter declaratory judgment that U.S. Patent No. 6,630,162 is invalid;

F. Enter declaratory judgment that U.S. Patent No. 6,770,295 is invalid;

G. Enter declaratory judgment that U.S. Patent No. 5,382,600 is unenforceable for inequitable conduct;

H. Enter an order dismissing Pfizer's Complaint, with prejudice, and denying the relief requested in the Complaint;

I. Declare the case exceptional and award Impax reasonable attorneys' fees and costs; and

J. Grant such other and further relief as the Court deems proper and just.

JURY TRIAL CLAIM

IMPAX CLAIMS TRIAL BY JURY AS TO ALL CLAIMS THAT MAY BE TRIED TO A JURY.

Dated: April 9, 2008

Respectfully submitted,

/s/ Stuart D. Sender
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